

## METHODS OF PROTEIN PURIFICATION AND RECOVERY

### ABSTRACT OF THE DISCLOSURE

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Improved methods for purification and recovery of interferon-beta (IFN- $\beta$ ) and compositions comprising substantially monomeric IFN- $\beta$  are provided. In one purification method, substantially purified IFN- $\beta$  or variant thereof is precipitated and then dissolved in a guanidine hydrochloride (HCl) solution. Renaturation of the protein occurs by dilution with a suitable buffer. A similar purification method absent the precipitation step is also provided. Following renaturation of the IFN- $\beta$ , residual guanidine HCl is removed by diafiltration or dialysis with a pharmaceutically acceptable buffer to prepare pharmaceutical compositions comprising substantially monomeric IFN- $\beta$ .

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